K053599

510(k) Premarket Notification
Spacelabs Medical, Inc.
Multigas Analyzer Module 91518 and Accessories
Summary of Safety and Effectiveness

APR 19 2006

Device Description:

The Spacelabs Medical Multigas Analyzer Module 91518 (Module 91518) is an easy-to-use modular unit in the Spacelabs Medical product family. The Module 91518 is a multigas sidestream analyzer intended to provide a measurement of the following parameters:

- CO_2 produced by the patient;
- O_2 and N_2O administered to the patient;
- Anesthetic agents administered to the patient which includes:
    - Desflurane;
    - Enflurane;
    - Halothane;
    - Isoflurane; and
    - Sevorflur-ane.
- Respiratory rate of the patient; and
- Calculated MAC and age-dependent MAC values.

The Module 91518 automatically identifies which anesthetic agent or mixture of anesthetic agents is present, and measures the concentration of the identified agent(s). An alarm is issued if a mixture of more than two anesthetic agents is detected.

The Module 91518 interfaces with all Spacelabs Medical monitors, except the SLP100. The monitor provides a numeric display for the gas concentrations and respiratory rate, and a waveform display for O_2 and CO_2. The Module 91518 is intended to be used for monitoring all hospitalized patients under the direction of qualified medical personnel.

Intended Use:

The Spacelabs Medical Multigas Analyzer Module 91518 (Module 91518) is intended to provide a means of monitoring a variety of gas concentrations and to alert clinical personnel when the concentration of anesthetic agent, oxygen, carbon dioxide or nitrous oxide falls outside of user defined limits. The Module 91518 is capable of automatically identifying which anesthetic agent(s) is being administered.

The Module 91518 is intended to be used with, and is controlled by, all Spacelabs Medical monitors, except the SLP100.

The Module 91518 is intended for use monitoring all hospitalized patients under the direction of qualified medical personnel.

Although the Module 91518 alarms when the duration between breaths exceeds user defined limits, it is not intended to be a primary diagnostic apnea monitor and/or recording device.

Test Discussion:	The Module 91518 is substantially equivalent in design concepts, technologies and materials to the combination of the Spacelabs Medical Module 90518 (K954962) and the Date-Ohmeda Compact Airway Module E-CAiOVX (K051092). The Module 91518 was validated through rigorous testing that, in part, support the compliance of the Module 91518 to the Standards mentioned in Section 6.1 of this submission. Additionally, the software for the Module 91518 was developed following a robust software development process and was fully specified and validated. The Module 91518 is the next generation in the Spacelabs Medical Integrated Multiparameter Module family of products for the Spacelabs line of patient monitors.
Test Conclusion:	The Module 91518 is substantially equivalent to its predicate devices in design concepts, technologies and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2006

Mr. Al Van Houdt
Director, Regulatory Affairs and Quality
Spacelabs Medical, Incorporated
5150 220th Avenue SE
P.O. Box 7018
Issaquah, Washington 98027-7018

Re: K053599
Trade/Device Name: Spacelabs Medical Multigas Analyzer Module 91518 and Accessories
Regulation Number: 868.1700
Regulation Name: Nitrous Oxide Gas Analyzer
Regulatory Class: II
Product Code: CBR
Dated: April 4, 2006
Received: April 5, 2006

Dear Mr. Houdt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

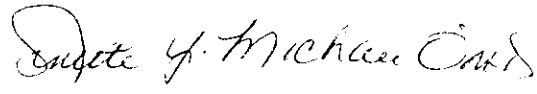
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K053599**

Device Name: Spacelabs Medical Multigas Analyzer Module 91518 and Accessories

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The Module 91518 is intended to be used with, and is controlled by, any Spacelabs Medical monitor, except the SLP100.

The Module 91518 is intended for use monitoring all hospitalized patients under the direction of qualified medical personnel.

Although the Module 91518 alarms when the duration between breaths exceeds user defined limits, it is not intended to be a primary diagnostic apnea monitor and/or recording device.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] General Hosp[illegible]

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